

REMARKS

Claims 1, 8, 14, 18, 31 and 38 are pending. Claims 1, 14 and 38 have been amended. Claim 40 has been added.

Because of the amendments do not introduce any new matter, Applicant respectfully requests that the amendments be entered.

Rejections Under 35 USC §103

The examiner asserts that Claims 1, 8, 14, 18, 31 and 38 are rejected under 35 USC §103 for the reasons previously set forth on paper No. 28, Section 5, pages 2-6 and the previous rejections cited in paper No.28, Section 5, pages 2-6 and paper #37.

From paper No.28, Section 5, pages 2-6 and paper No.31, pages 2-12 and paper #37.

Hadvary et. al. US Patent # 4,598,089 recites oral administration of Xenical (Orlistat). Xenical is a lipase inhibitor resulting from the byproduct of the cultivation of *Streptomyces toxytricini*. Xenical is an N-formylleucine derivative used for the treatment and/or prevention of obesity. This product is not related to an anti-lipase antibody structurally or functionally. Xenical binds the active site of the enzyme making it inactive. The present invention is a polyclonal antibody that bind to several areas of lipase. The present invention does not try to prevent or treat obesity or hyperlipemia as Hadvary et al. but to reduce the digestion and absorption of fat in the gastro-intestinal tract of the mammal. By using the antibody of present invention with food or included as part of a food we do not have to worry about how much fat is in it because fat digestion is going to be inhibited or decreased, in other words, one can still eat the same tasty-full-fat food without worrying of the fat-calories or off-taste and off-consistency of low-fat and fat-free products.

Moloney (Livestock Prod, Sci. 1995, 42:239-245) and Flint (Proc. Nutrition Soc. 1992, 51:433-439) suggest "friendly methods to increase lean content in meat" that "decrease body fat, backfat thickness and loin fat" (see abstract) by neutralizing, inhibiting or mimicking gastro-intestinal endocrine compounds and/or adipose cell components. The present invention does not try to increase lean body mass or suggest any effect on the adipose

tissue, what it suggest is the decrease in fat absorption limited to the gastro-intestinal tract of the animal. The present invention does not try to reduce the fat content of meat or improve the quality of meat by immunological methods. The present invention does not try to treat or prevent adiposity, it tries to reduce fat absorption of fat present in foods by decreasing lipase activity in the gastro-intestinal tract of mammals.

Ohkaru et al and JP 02150294 disclose the use of monoclonal anti-lipase antibodies for the quantification and activity of lipase in in-vitro test. They do not suggest the use of orally fed antibodies for the inhibition of lipase in-vivo or their use on the inhibition of fat absorption in the gastro-intestinal tract of an animal. These monoclonal antibodies are one for detection of lipase and the other for inhibition of lipase activity. They suggest uses on in vitro diagnosis, measurement of lipase (Elisa) and specific staining of pancreatic tissue as described on page 5 paragraph 5 of the patent “ their purpose is therefore to propose antibodies suitable for use in measurement methods which enables lipase measurements to be performed simply, rapidly and with good sensitivity”.

Combination Moloney (Livestock Prod, Sci. 1995, 42:239-245), Flint (Proc. Nutrition Soc. 1992, 51:433-439), Ohkaru et al and JP 02150294. The present invention do not suggest an effect on the adipose tissue, an improvement on the quality of meat or a measurement of lipase or lipase activity. The combination of above teachings might suggest the inoculation (intra-peritoneally or vascularly) of anti-lipase monoclonal antibodies to prevent adiposity by binding lipase in the adipocytes (fat depots) with the hope of obtaining a leaner animal. The present invention decreases the utilization of fat present in food by inhibiting lipase in the gastro-intestinal tract.

Paper #31 pages 7-8. As described: “that motivation existed for inhibiting pancreatic lipase, a method existed to inhibit lipase, antibodies are known that inhibited lipase, and antibodies were conventionally and successfully used in animal feed, orally administered for reasons of animal husbandry”. There is motivation to decrease lipase in order to decrease fat absorption. There is a method to inhibit lipase, it is true but it is a drug (not a derived animal protein like an antibody) that have induced many side effects to people consuming it. Antibodies are known to inhibit lipase, it is true but these monoclonal antibodies were and are used for measurement the activity and concentration of lipase, there is no reference to either

used them as therapeutic either systemically or orally, also monoclonal antibodies need to be humanized to used systemically and enterically protected for oral used if effective. Orally antibodies are effective, it is true, several patents have been issued on the used of oral avian antibodies having the same motivation as described on paper #31 pages 7-8. A list of patents were described in the previous amendment; all these patents refers to avian antibodies for the treatment or prevention of diseases or hormonal regulation, none of them refers to digestion modifiers which is the main objective of the present invention. In the specification, examples 5 and 6 show that mice fed the anti-lipase antibody had a lower body weight gain even though they had the same level of intake than mice fed no antibody; this suggest that the antibody has modified the process on how feed was utilized (Patents referred on the previous amendment, Cook, et al. US Patent # 5,989,584, Cook, et al. US Patent 5,827,517, Stolle, et al. US Patent # 5,932,250, Kodama , et al. US Patent # 6,419,926 , Williams, et al. US Patent # 6,365,158, Kink , et al. US Patent # 6,290,960, Williams , et al. US Patent # 6,080,400, Kink , et al. US Patent # 5,736,139, Stafford , et al. US Patent # 6,346,247, Sterling , et al. US Patent # 5,753,228, Kink , et al. US Patent # 6,395,273, Adalsteinsson , et al. US Patent # 6,086,878, Pimentel US Patent # 5,741,489.

Claim Rejections Under 35 USC §112

Claims 1, 8, 14, 18, 31, and 38 are rejected under 35 USC 112. The specification suggest the use of a porcine pancreatic extract containing lipase (page 4 of the specification). This pancreatic extract also contains other enzymes like amylase and proteases. Claims have been amended to avoid rejection.

New grounds of Objection, pages. 11 & 12 of paper No 31: the added material which is not supported by the original disclosure is as follows: "By inhibiting lipase through binding the ingested fat will not be absorbed and the fat itself will be excreted"; binding is between the antibody and lipase, examiner's objection is accepted.

Based on the above amendments and remarks, reconsideration an allowance of the pending application is believed to be warranted.

Respectfully submitted,



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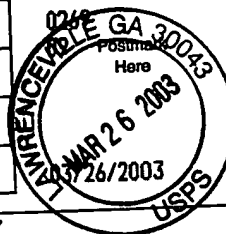
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